

ditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: December 14, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,000 against John E. Stephens and \$500 against Andrew J. Collinsworth.

3864. Misbranding of inositol hexanitate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets, and sulfadiazine tablets. U. S. v. Joseph K. Carlisle (Carlisle Drug Store). Plea of guilty. Fine of \$500, plus costs. (F. D. C. No. 33729. Sample Nos. 34340-L, 34347-L, 34348-L, 34354-L, 34355-L, 34453-L.)

INFORMATION FILED: November 20, 1952, Southern District of Illinois, against Joseph K. Carlisle, trading as Carlisle Drug Store, Chillicothe, Ill.

ALLEGED VIOLATION: On or about February 20, 25, and 28, and March 3, 1952, while quantities of *inositol hexanitate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets, and sulfadiazine tablets* were being held for sale at the Carlisle Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *inositol hexanitate and phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *inositol hexanitate and phenobarbital tablets* and *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 3, 1952. A plea of guilty having been entered, the court imposed a fine of \$500, plus costs.

3865. Misbranding of Combisul-DM tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Irving L. Rutkoff (Fayetteville Pharmacy). Plea of guilty. Fine, \$104. (F. D. C. No. 31298. Sample Nos. 74167-K, 74169-K, 74171-K, 74174-K, 74176-K.)

INFORMATION FILED: May 15, 1952, Northern District of New York, against Irving L. Rutkoff, trading as the Fayetteville Pharmacy, Fayetteville, N. Y.

ALLEGED VIOLATION: On or about October 30 and November 1, 8, and 27, 1950, while quantities of *Combisul-DM tablets, dextro-amphetamine sulfate tablets,*

and *pentobarbital sodium capsules* were being held for sale at the Fayetteville Pharmacy after shipment in interstate commerce, the defendant caused 1 bottle of the *Combisul-DM tablets* and 1 bottle of the *dextro-amphetamine sulfate tablets* to be dispensed without the prescription of a physician to purchasers in the original bottles in which the tablets had been shipped in interstate commerce; and, in addition, the defendant caused various quantities of the *pentobarbital sodium capsules* and the *Combisul-DM tablets* to be repacked and dispensed without prescriptions, which acts of the defendant resulted in the dispensed drugs being misbranded.

NATURE OF CHARGE: *Combisul-DM tablets* and *dextro-amphetamine sulfate tablets* (dispensed in original bottles). Misbranding, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use. (The bottles in which the tablets were shipped in interstate commerce bore no directions for use since they were exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing such drugs without a physician's prescription caused the exemption to expire.)

Pentobarbital sodium capsules and *Combisul-DM tablets* (repackaged portions). Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Combisul-DM tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the repackaged *pentobarbital sodium capsules* and *Combisul-DM tablets* failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *Combisul-DM tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court imposed a fine of \$104.

3866. Misbranding of Nembutal capsules and Benzedrine Sulfate tablets. U. S. v. Lew Wallace (Wallace Rexall Drugs), John W. Gordon, Jr., and George M. Smith. Pleas of *nolo contendere*. Fine of \$50 against each defendant. (F. D. C. No. 28136. Sample Nos. 53420-K, 53885-K, 53890-K, 53898-K, 53900-K, 53913-K, 53968-K, 53969-K, 54126-K.)

INFORMATION FILED: September 14, 1950, Southern District of Mississippi, against Lew Wallace, a partner in the firm of Wallace Rexall Drugs, Laurel, Miss., and against John W. Gordon, Jr., and George M. Smith, pharmacists in the business.